In Re:

Digitek

Scott Talbot

January 25, 2010

Confidential – Subject to Further Confidentiality Review

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EXHIBIT C-3

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

In re: DIGITEK
PRODUCTS LIABILITY LITIGATION

MDL No. 1968

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(This document relates to all cases.)

CONFIDENTIAL - SUBJECT TO FURTHER
CONFIDENTIALITY REVIEW

VIDEOTAPED ORAL DEPOSITION OF
SCOTT TALBOT
DAVIE, FLORIDA
January 25, 2010
9:17 a.m.

Videotaped oral deposition of SCOTT TALBOT, pursuant to notice, taken by Plaintiffs, at the offices of Morgan & Morgan, LLP, 6824 Griffin Road, Suite 230, Davie, Florida, before Kelli Ann Willis, a Registered Professional Reporter, Certified Realtime Reporter and Notary Public within and for the State of Florida.

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ALSO PRESENT:

Sylvanus F. Holley, Video Operator

to in this letter.

Q. Well, they help us out with that. They actually, if you go to -- give me one second here.

If you go to the second page, Actavis 436183, the second sentence says -- starts out with, "We have."

Have you got it? Okay.

"We have included OOT results and deviations from prescribed processing steps" -- actually, no. Strike that. That's not what I want to read. It would help if I would have highlighted the right spot.

Take a look at the Actavis 0436185, the first page of what is titled, "Actavis Totowa Released Batches Associated with an OOS."

I'm correct in saying that OOS is out of specification?

A. Yes.

Q. You were aware that there were issues with out-of-specification products during this timeframe?

A. Yes.

Q. And, unfortunately, we can't read the lists, the first page or the second page, but we get to the -- not the third page, but the fourth, there

Having seen this list, does it refresh your recollection if out-of-specification test results were a concern with Actavis in early January 2007?

A. Yes.

Q. And does it refresh your recollection as if you were briefed on this particular issue by the president of Actavis in January of 2007?

A. I don't know.

Q. You don't remember or you don't know?

A. I don't know if it was the president that would be briefing me on these particular OOSs.

Q. Were you briefed by anyone on this issue at Actavis in this time frame?

A. I don't know.

Q. You don't remember or you don't know?

A. I can't recall for sure if I was briefed specifically by one person or by an individual telling me about these OOSs.

Q. So is it fair to say you do remember having the conversation; you don't know if it was one person or more?

A. I don't recall having the conversation.

Q. You don't recall having the conversation.

Did out-of-specification test results become a concern with you throughout the year or throughout your time at Actavis, as site quality head or site head for quality -- let me strike that and rephrase it.

As site head for quality at the Totowa facilities, did out-of-specification test results ever become a primary focus for you?

A. Yes.

Q. And when did that take place?

A. As the site head of quality, OOSs are always something that you monitor. So it is not specific to Actavis Totowa. It would be specific to any company that I worked for.

Q. And it is also something that an FDA inspector, during a GMP inspection, would look at and observe; is that correct?

A. Yes.

Q. And you would agree that if during the course of that inspection, if there were no issues with out-of-specification results, then there would be no write-up on out-of-specification results?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Yes.

BY MR. MILLER:

Q. So my focus is or my question is, did it become a concern of yours as site head of quality at Actavis due to observations by the FDA?

A. No.

Q. Start with the paragraph that starts with, "Your letter also," and it's on Actavis 0436183.

A. Yes.

Q. "Your letter also requests that we provide a listing of released lots of drug products that remain within expiration, that were associated with any OOS test results when manufactured, and explanations of actions taken to ensure they are suitable for use.

"This list is enclosed as attachment A and identifies 38 released lots, provides expiry date information for them, and identifies OOS results associated with them."

Did I read that correct?

A. Yes.

Q. And do you agree that that is the list that we looked at two pages back?

A. Yes.

Q. So you're familiar with the fact that production was shut down for 65 products?
A. Yes.
Q. Am I correct in saying there were 65 products?
A. I don't know.
Q. Okay. Do you have experience with any of these former companies in which every product line was shut down?
A. Yes.
Q. Which company?
A. The IVAX plant that was in Puerto Rico, which is formerly IVAX, the TEVA facility in Puerto Rico.
Q. There came a time production was ceased?
A. Yes.
Q. That was due to an FDA inspection?
A. Yes.
Q. And how many products were being produced at IVAX in Puerto Rico?
A. I don't know.
Q. More than 10?
A. Yes.
Q. More than 50?

Have you got that?

A. Yes.

Q. "We also have focused on the structure and leadership of the Quality organization and have restructured it. Henceforth, there will be five senior management positions: Site Head of Quality, Quality Assurance Director, Quality Control Director, Quality Systems Director and Validation Director. Scott Talbot has been hired as the new Site Head of Quality. His credentials are provided in Attachment B."

Did I read that correctly?

A. Yes.

Q. Did you know that you were specifically hired to fill a position that hadn't been filled in the past?

A. Yes.

Q. Did anyone ever tell you that your credentials were provided to the FDA?

A. I don't remember.

Q. You don't recall being asked for a copy to include in this letter?

A. No.

Q. It goes on to say, "Suffice it to say that

Mr. Talbot already has proven himself to be dedicated to quality systems improvements, including laboratory practices.

"He has the knowledge of FDA requirements and guidances, industry standards and critical thinking skills to elevate our standards and cGMP awareness to a higher level that assures compliance.

"We continue recruitment efforts for the open positions."

When you were hired, did you feel that the GMP awareness and standards needed to be elevated? Let me ask that in a better way.

Was elevating the GMP standards at Actavis a primary focus for you when you were hired?

A. Can you define "elevated"?

Q. Certainly.

Were there GMP violations that needed to be addressed when you were hired?

A. There was always room for improvement. I don't know if "violations" is a word that I would agree with.

Q. If there is a -- well, you've seen 483s. We already talked about you reviewed the '07 one.

A. Yes.

Q. Are you familiar that there were two of FDA inspections resulting in 483s in 2006?
A. Yes.
Q. Did you ever have an opportunity to review those?
A. The August inspection.
Q. Did you review the August '06 inspection in the ordinary course of your work as site head of quality?
A. Yes.
Q. And do you recall there being several observations in that 483?
A. Yes.
Q. Typically, when there is an observation and it is spelled out, like observation 10 gives you information, would you agree that those are typically addressing a violation of a GMP?
A. You would have to go back and look at exactly what the investigator was looking at before you can make a determination.
Q. Okay. And if we go back to the EIR, the inspection report, would that typically explain what the investigator was looking at?
A. Yes.

Q. Well, when you, now going back, when you went back and reviewed the second FDA 483 from 2006, did you feel that there were violations of GMPs that needed to be addressed?

A. There was room for improvement, yes.

Q. Does your "yes" mean that there were violations? Room for improvement doesn't really answer the question.

My question is, were there GMP violations that you needed to address from the two thousand --

A. I don't recall.

Q. All right.

MR. MILLER: I would like to mark as Exhibit 150.

(Thereupon, the referred-to document was marked by the court reporter for Identification as Deposition Exhibit 150.)

THE WITNESS: Thank you.

BY MR. MILLER:

Q. Sir, I will represent to you this is the attachment.

MR. ANDERTON: What is it?

MR. MILLER: This is 150, yes.

MR. ANDERTON: Okay.

obviously? Is that correct?

A. Yes.

Q. The quality in the lab, does that come from the quality systems director or the quality control?

A. The quality control director from the quality control laboratory.

Q. Well, the quality control laboratory would report to the quality control director; correct?

A. Yes.

Q. As the site head of quality for Totowa -- when I say "Totowa," I'm encompassing Little Falls, Taft. Is that correct, it's all under the title of Totowa?

A. Yes.

Q. As the site head of quality for Totowa, do you have the authority, if it's known to you -- if it's known to you that there's a GMP violation issued, do you have the authority, as site head of quality, to discontinue or not release a product?

A. Yes.

Q. Do you recall exercising that authority while you were the site head of quality?

A. Yes.

Q. On how many occasions would you have exercised that authority?
A. I don't know.
Q. More than 10?
MR. ANDERTON: Objection. I'm going to caution you to limit your answers to Digitek only, please.
THE WITNESS: I don't know.
BY MR. MILLER:
Q. Do you know if you ever exercised your authority, as site head of quality, to not release a Digitek lot or batch?
A. I don't remember.
Q. I'm going to hand to you what was previously marked as Plaintiff's Exhibit 49.
(Thereupon, a discussion was held off the record, after which the following proceedings were held:)
BY MR. MILLER:
Q. You are familiar with the current good manufacturing practices?
A. Yes.
Q. You're familiar with them being referred to as the CFR Chapter 210 and 211?

Q. All right. Then I guess my question would be this: Packaging material, would you, as a site head of quality, be in a position where you could approve or reject packaging material?

A. Yes.

Q. Is it true for all of these, if I go down the line, labeling drug products?

A. Yes.

Q. I guess my thought there is, there's no separate quality for manufacturing; if there's a manufacturing issue, you're still the site head for that quality as well?

A. Yes.

Q. Like even if a machine caught on fire, does that fall under your quality care and control?

A. Only if it impacts product.

Q. Okay. Fair enough.

So there's no quality assurance -- and I'm beating this to death.

MS. CALLSEN: I'm picturing Scott running in with a fire hose.

BY MR. MILLER:

Q. For equipment, there's no quality assurance separate and apart to the equipment that

wouldn't ultimately report to you?

A. Can you ask the question again?

Q. Certainly.

A. I don't think I understand it.

Q. I hate to beat this to death, but there's no quality assurance in the production side of the house, away from the lab or the packaging or labeling, that would not ultimately report to you?

A. No. I'm not sure if I answered that question correctly. Can you ask it again? It seems like there's a double negative in there.

Q. Every aspect of quality, like if there's a quality assurance department at Totowa, say, for a particular piece of machinery, ultimately any document or report coming from that quality assurance would make its way to you, as the site head of quality?

A. Yes.

Q. I'm going to hand you what I'm going to mark as Exhibit 151.

(Thereupon, the referred-to document was marked by the court reporter for Identification as Deposition Exhibit 151.)

this case?

A. It was part of a follow-up to previous letters that had been written to the FDA.

Q. Follow-up to what previous letters?

A. To provide updates to the compliance officer on the improvements that were being made to the Totowa site.

Q. And those improvements were as a result of observations found during FDA inspections; is that correct?

A. The improvements that we were conveying to the FDA were specific to the observations.

Q. The second paragraph starts out with "QSIP." Do you see it?

A. Yes.

Q. "The QSIP program is based on reviewing individual quality systems and determining if a remediation is required."

You're familiar with the term CAPA, correct?

A. Yes.

Q. Isn't it -- correct me if I'm wrong, but if there is an FDA observation, CAPA is corrective and preventative actions?

A. No.
Q. What is CAPA?
A. Corrective Action, Preventive Action.
Q. Is that a standard program in place that is used to address issues found during FDA inspections?
MR. ANDERTON: Objection.
THE WITNESS: No.
MR. ANDERTON: You may answer.
BY MR. MILLER:
Q. What is CAPA?
A. CAPA is a standard program within the quality systems to address any type of issue that may require corrective and preventive actions. It is not specific to the FDA.
Q. Okay. You would agree with me that -- did you, as the site head of quality for Totowa, utilize the CAPA program when addressing any FDA 483 observations?
MR. ANDERTON: Objection.
BY MR. MILLER:
Q. No?
MR. ANDERTON: Form. You may answer.
THE WITNESS: No.

BY MR. MILLER:

Q. What is the difference between -- well, what is QSIP?

A. Quality System Improvement Plan.

Q. And how would you differentiate CAPA from QSIP?

A. QSIP is an overall program. It's a tool to keep management informed of improvements that are being made to the entire quality system.

Q. Fair enough.

Were you involved also in CAPA while you were the site head of quality at Actavis?

A. Yes.

Q. And then what is CAP?

A. I don't know.

Q. I have seen -- I have read, I believe, it's Corrective Action Plan.

Would you consider Corrective Action Plan and Corrective Action Preventive Action to be the same thing, if you know?

A. I don't know.

Q. Okay. Do you know if out-of-specification findings were one of the issues addressed in the QSIP plan?

A. I would have to answer the way you -- no.
Q. Explain.
A. The QSIP program was addressing on how we handled OOSs, not specific to one or existing OOSs. It was providing a system formalizing the handling of OOSs.
Q. So it wasn't drug-specific; it was across-the-board?
A. Yes.
Q. Is there at Actavis, or while you were site head for quality, was there a standard operating procedure written for how out-of-specification results were handled?
A. Yes.
Q. And was it one document that addressed how all products were handled or was an SOP for each product?
A. One SOP.
Q. And were you aware of any, at the time, violations noted of that SOP?
A. No.
Q. Was there an SOP in place when you began your work at Actavis in January of '08, if you recall?

Q. Would you, in your ordinary course of work at Actavis as a site quality head, would you have gone back and read this?

A. Yes.

Q. And why would it be important for the site head of quality to go back in time and read a 483 from the previous year?

A. To assure that our systems are being improved and to avoid future 483s.

Q. We go to -- well, observation one states: "The quality control unit lacks authority to fully investigate errors that have occurred."

Now, that's an observation from an FDA representative who was personally at the facility; is that correct?

A. Yes.

Q. And as written, is that a violation of a GMP?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: As written, yes.

BY MR. MILLER:

Q. Would failure to investigate an out-of-specification result fall under that, if the

quality control unit lacks authority to fully investigate errors that have occurred, or is this a separate problem?

A. Yes.

Q. So OOS would fall under this?

A. Yes.

Q. And in reviewing this document, taking over as quality site head, is this one of the issues that -- or is this one of the findings that lead you to have someone or yourself rewrite the SOP on out-of-specification issues?

MR. ANDERTON: Objection, you may answer.

THE WITNESS: No.

BY MR. MILLER:

Q. All right. In reading this, as a site quality head, would you have taken any action from these specific findings about observation 1?

A. Possibly.

Q. Take a look at Observation 4.

It says, "Observation 4: Written records are not always made of investigations into the failure of a batch or any of its components to meet specifications."

Did I read that correctly?

A. Yes.

Q. Do you recall reviewing this in the ordinary course of work, as the site head of quality for Actavis?

A. I don't recall.

Q. It goes on to say, "Specifically, investigations were not conducted when out-of-specification results were generated, samples were retested, and the original results were not invalidated."

This observation, as I read it, would you agree, as written, that it's a violation of GMP?

A. Possibly.

Q. Why possibly?

A. I would need to review each of the specifics that the FDA investigator looked at and determine whether it was the way that the -- presentation of the data or was it the way that the investigator interpreted the data.

Q. Okay. But would you agree that as a result of their observations that improvement or changes needed to be made?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Possibly.
BY MR. MILLER:
Q. As written, is this a violation of the then current SOP at Actavis?
A. I don't know.
Q. You'd agree with me that in a pharma-ceutical lab, out-of-specification findings are going to happen, correct? You wouldn't expect to produce products for years and not have an out-of-specification finding; is that fair?
A. Possibly.
Q. And then you would also agree that there are procedures in place to ensure that the batch meets the purity, strength, quality that it's supposed to have; is that correct?
A. Yes.
Q. And you would agree with me that simply retesting is -- when it comes to out-of-specification as per the GMP is not enough; is that correct?
MR. ANDERTON: Objection.
BY MR. MILLER:
Q. You would have to investigate why there was an out-of-specification?

MR. ANDERTON: You may answer.

THE WITNESS: Most of the time.

BY MR. MILLER:

Q. Most of the time?

A. Yes.

Q. Is it true for Digitek?

A. Yes.

Q. Well, that's a tough one.

Is it true for Digitek that it's most of the time or is it true for Digitek all the time?

A. That was two questions again.

Q. It was an aura.

For the product Digitek, if the laboratory finds an out-of-specification result -- actually, correct that.

For the product Digitek, if the quality unit finds or is reported to them that there's an out-of-specification finding, it is important that not only is an additional test done to show in-specification findings, that they have to go beyond and investigate why the out-of-specification happened?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Most of the time.

BY MR. MILLER:

Q. Can you think of an example when you wouldn't have to do that?

A. You're using the term "investigation," which maybe we don't agree upon.

Q. Okay. What word would you use?

A. In the OOS system, within the laboratory, a laboratory review occurs first.

Q. Okay.

A. That laboratory review is an internal laboratory document to assure that no errors occurred during the -- or obvious errors occurred during sample preparation or testing.

Q. Okay.

A. For example, a calculation error or an incorrect method was used.

If, after going through that scenario, they do not find a root cause, then it goes into a full blown, what I would call an investigation.

Q. I think I can word the question right now.

If, for the product Digitek, during the lab review, there is found an out-of-specification finding, and it is not the result of a calculation

error or incorrect method, that there is a requirement that additional testing be done to show that it's in-specification, and also there needs to be an investigation that goes into why the out-of-specification happened?

A. Yes.

Q. I have to try to remember all of those words again.

Let me ask you this way: For the product Digitek, if there is an out-of-specification finding, either laboratory or anywhere else, is there a requirement that there is a second testing done to show that it's in-specification, and also an investigation required setting aside if it was a calculation error or an incorrect method?

MR. ANDERTON: Objection, form.

You may answer.

THE WITNESS: Yes.

BY MR. MILLER:

Q. Okay.

A. That was a long question, but I think I followed you on that.

Q. The same holds true, if there is an out-of-specification finding, that concept holds

true if it's in the lab or somewhere else?

A. If the lab does not find an identified cause laboratory error, then, yes, it goes through a full investigation and retest.

Q. Go to Observation 5 for the August 2006 FDA inspection.

"Observation 5: Input to and output from computer are not checked for accuracy."

Do you recall reviewing this specific issue when you worked for Actavis?

A. Yes.

Q. Were you involved in improving or did you find that improvement needed to be made in the input to and output from computer such that they were checked for accuracy?

A. I don't recall.

Q. It goes on to say, "Specifically, audits were not conducted of the TotalChrom Data Acquisition System used to run the HPLC instruments during analysis of drug products."

Were you involved, as site head for quality, in initiating audits regarding the Total-Chrom Data Acquisition System?

A. Can you define what you mean by "audits"?

Q. Well, did you understand, when you read this document that was prepared by an FDA inspector, what they meant by "audits"?
A. Data review by a second person.
Q. Okay. Data review by a second person. As the site head for quality, did you ensure that data was reviewed by a second person in quality?
A. Yes.
Q. Did you do it as a result of this write-up?
A. No.
Q. How did you come to find out that data was not being reviewed by a second person?
MR. ANDERTON: Objection.
THE WITNESS: If it wasn't --
BY MR. MILLER:
Q. Was there any other source of you being informed that data wasn't reviewed by a second person with the TotalChrom Data Acquisition System?
MR. ANDERTON: Objection.
You may answer.
THE WITNESS: Internal review without FDA oversight.

BY MR. MILLER:

Q. So your testimony is that internal review lead you to believe that data was not being reviewed by a second person regarding the TotalChrom data; is that correct?

A. Possibly.

Q. So as you sit here, you're not sure?

A. I'm not sure, and I would need to see specifically what the FDA was looking at to write this observation.

Q. You agree that this observation, as written, is not specific to any product?

A. Yes.

Q. And you agree that, as written, it would involve all products that were being tested utilizing the TotalChrom Data Acquisition System?

A. Yes.

Q. It's across-the-board problem for products using the TotalChrom data?

A. Your assumption is that it is a problem.

Q. Your assumption is it is not a problem?

A. I can't answer that question without knowing more specifics about this observation.

Q. Have you ever known observations in FDA

483s to be exemplary remarks or pats on the back? Does the FDA ever use observations to say that you are doing this well?

A. No.

Q. Are observations ever used to say that this meets requirements but it could be better?

A. No.

Q. Are observations used to point out things that are not in compliance with cGMP?

A. Yes.

Q. Let's take a look at Observation No. 8. Again, the FDA findings from their inspection of GMP compliance in August of '06, Observation No. 8 reads: "Examination and testing of samples is not done to ensure that in-process materials conform to specifications."

Did I read that correctly?

A. Yes.

Q. Do you recall this issue as something that you would have reviewed or set up procedures to improve when you first read this?

MR. ANDERTON: Objection.

THE WITNESS: I don't recall.

MR. ANDERTON: You may answer.

THE WITNESS: I don't recall.

BY MR. MILLER:

Q. It goes on to say, "Specifically, on numerous occasions, quality assurance personnel failed to detect tablets and capsules which did not meet in-process specifications for tablet weight and thickness."

As a site head of quality, you also would be the overseer of issues such as tablet weight and thickness?

A. Yes.

Q. Is a tablet that is not the proper weight or thickness, is that out-of-specification?

A. Yes.

Q. So would that -- it goes on to say, SOP 016, "Routine tablet press overcheck requires a new set of samples to be taken when out-of-specification results are encountered. This did not occur." And then it goes on to give examples.

Does that refresh your recollection of -- does that help you to recall this might have been an issue that you addressed?

A. No.

Q. The SOP 016, routine tablet press over-

check, that is a different SOP than the SOP for out-of-specification, correct?

A. Yes.

Q. But you would agree -- or tell me if I'm wrong, would a tablet that's not the proper weight and thickness, would that also require review and application of the out-of-specification SOP?

A. No.

Q. Why?

A. The out-of-specification SOP is specific to the laboratory.

Q. So is it your testimony that if there is an out-of-weight or thickness tablet, then there is no requirement or duty of the laboratory to be involved?

A. No.

Q. That's not what you're saying?

A. No.

Q. What is -- if an oversized -- if a tablet of the improper weight or thickness is found, as discussed here in this observation, what responsibilities and/or duties would the laboratory have with that tablet?

A. As part of the investigation, they may be

involved in doing additional testing within the laboratory.

Q. And that would be a quality -- that is the responsibility of quality, to determine if that tablet would need to go to the laboratory or that lot or batch would need to go to the laboratory to be tested?

A. Yes.

Q. And that would fall under your title?

A. Under my responsibility.

Q. Your responsibility. Okay.

"Observation 9: Deviations from written production and process control procedures are not recorded and justified. Specifically, there is no assurance that all manufacturing deviations are documented," and it goes on to give examples.

A. Okay.

Q. Does this stand out as one of the issues that you would have addressed when taking over as site head of quality in January of '07?

A. No.

Q. Is this an issue that you would have assigned to someone else in quality to take a look at?

A. Possibly.

Q. Early in your employment at Actavis, did you feel it necessary to do an internal audit, did you elect to -- strike that.

Early in your employment at Actavis, did you set up an internal audit?

A. No.

Q. Was an internal audit done as a result of an ordinary scheduling of internal audits?

A. While I was at employed at Actavis Totowa, yes.

Q. Okay.

In February of '07, you are letting the FDA know you are filling a spot, site head of quality, that didn't previously exist. The president of the company is letting the FDA know that you have been hired and you are very proficient in GMPs.

Will you agree that GMP compliance was a concern at the company in February of '07?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Would I agree that GMP compliance was a concern of the company?

Possibly.

BY MR. MILLER:

Q. Was it a heightened concern, due to the previous FDA 483 reports and the warning letter?

A. You are using the word "concern." I think there was a heightened focus on it.

Q. A heightened focus, that is fine. A heightened focus.

If there's a heightened focus on GMP in 2007 and you are the site head of quality and you reviewed this FDA 483, did you use this as a stepping stone to determine what specifically to focus on?

A. As -- in addition to other things.

Q. Okay. And in addition to what other things?

A. Internal review, not an audit, but an internal review. As I was hired, I went through procedures and documents, and verified if there were areas for improvement.

Q. Internal review, did you conduct an internal review shortly after taking the position of site head of quality?

A. Continuously. It wasn't a defined start

and stop point. It was an internal, every document, every system.

Q. You felt your job, your description, your function daily was an internal review?

A. Yes.

Q. Was that due to the heightened focus on GMPs at Actavis, or was that what you considered to be your ordinary duty?

A. Ordinary duty.

Q. You agree that an FDA inspection of GMPs can result in a 483, and we have already stated that that can result in a warning letter, correct?

A. Yes.

Q. What is the next action or one of the next actions that can be taken by the FDA beyond that?

A. Injunction.

Q. Injunction.

An injunction, do me favor -- another action, would you agree, is that they can shut down production, or the result can be shut down production of the assembly line or the product line?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: If you're asking if FDA has

the authority to shut down production?
BY MR. MILLER:
Q. Yes.
A. I don't know.
Q. Okay. Well, explain to me what you mean by "an injunction."
A. An injunction is where they actually come in and seize all of the products that have been manufactured, and they put locks on the doors to prevent more distribution of the products.
Q. That is one -- that's beyond a warning letter?
A. Yes.
Q. Okay. Can it come to a point in time that a pharmaceutical company would cease production due to violations of GMPs?
A. Yes.
Q. You would agree that's in between a warning letter and an injunction?
A. Yes.
Q. Well, would you agree that a part of the reason you are having this, a heightened focus on GMPs, is because of the warning letter that was filed in 2007?

A. In addition to.
Q. In addition to other things?
A. Yes.
Q. And is part of that heightened focus also to prevent the next step, which would be the shutdown of production of the plant?
MR. ANDERTON: Objection.
You may answer.
BY MR. MILLER:
Q. It's okay to answer.
A. Possibly.
(Thereupon, a discussion was held off the record, after which the following proceedings were held:)
MR. MILLER: Let's take a break.
THE VIDEOGRAPHER: Going off video record.
(Thereupon, a recess was taken, after which the following proceedings were held:)
THE VIDEOGRAPHER: We are back on video record, approximately 10:54, with Tape 2, videotaped deposition of Scott Talbot.
BY MR. MILLER:
Q. Before the break, we were taking a look at what had been previously marked as Exhibit 68, and

it's the FDA 483, observations from the August '06 inspection. If you would, take a look at Observation 10. It's on the lower right, it says Page 7 of 9.

A. Okay.

Q. And Observation 10 is not the one I want you to take a look. If you turn the page and go to Observation 12, Page 8 of 9.

A. Okay.

Q. Observation 12 says: "Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils used in the manufacturing, processing, packaging or holding of a drug product."

Sir, as written, is that a violation of GMP?

A. Yes, as written.

Q. Were you aware that there was a response to the FDA from Actavis, that Actavis agreed with the findings of this inspection?

A. I don't recall.

Q. I'm going to hand you what was previously marked as Exhibit 69.

MR. ANDERTON: Thank you.

BY MR. MILLER:

Q. As written, is this a violation of the GMP?

A. Yes, as written.

Q. And given the fact that the company agrees with the observation, then does that make it a violation of GMP, either as written or not as written -- as written, it is a violation of GMP?

MR. ANDERTON: Objection, form.

You may answer.

THE WITNESS: As written, yes.

BY MR. MILLER:

Q. And it is a violation of a GMP that the company agreed to?

A. I would say this letter, as written, says that it agrees to this observation.

Q. Did you ever have conversations with Nasrat Hakim regarding her agreeing or not agreeing with the observations on the 483?

A. No.

Q. Are you aware of cleaning and maintenance becoming an issue with the product Digitek during your employment as site head of quality for Actavis?

A. No.

Q. Were you aware of duct tape ever being used on equipment while you were site head of quality?
A. No.
Q. Were you aware that duct tape had been used in the past on equipment?
A. No.
Q. You never addressed a duct tape concern at all while you were employed at Actavis?
A. There was never duct tape on the equipment when I was employed at Actavis.
Q. Fair enough.
Did you review the Establishment Inspection Report that went along with this?
A. No.
Q. Are you aware that it is the FDA's practice to send the Establishment Inspection Report to the company to review?
A. Yes.
Q. Were you aware that the Inspection Establishment Report for this particular inspection was sent to Actavis?
A. No.
Q. Would it have helped you, in your role as

out-of-specification?

A. Yes.

Q. Given that that is what OOS stands for, do you agree that I read it correctly?

A. Yes.

Q. And does that reflect the findings and the observations, Observations 1 through 15?

A. I don't know.

Q. Would they list on the EIR observations above and beyond those reported in the 483?

A. No.

Q. Deficiencies in so many areas, is that typical for the findings of an 483, in your experience?

A. It is not atypical.

Q. If you were to use the term pass/fail for an inspection, would you say you passed -- not you -- would you say that Actavis passed or failed this 2006 inspection?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: It's hard to say.

BY MR. MILLER:

Q. If an FDA inspection of GMP compliance

Q. Was that the sole purpose for the meeting of the team, was it to discuss this letter?
A. Yes.
Q. Would heightened focus on GMPs be one of the issues that was discussed?
A. Again, a heightened focus is always something that we looked into. But this was specifically to review this warning letter.
Q. Do you recall anyone on the team feeling that the facts of the letter were not accurate?
A. I don't recall.
Q. Was QSIP created as a response to this letter?
A. No.
Q. Was QSIP in response to any particular event?
A. I don't know.
Q. Was the QSIP program in place when you were employed in January of 2007?
A. Yes.
MR. MILLER: I'm going to hand you what I'm going to mark as Plaintiff's Exhibit 154.
(Thereupon, the referred-to document was marked by the court reporter for Identification

as Deposition Exhibit 154.)

MR. ANDERTON: Thank you.

BY MR. MILLER:

Q. I represent to you that this is a document provided in your custodial file from Actavis, entitled Minutes from several dates, QSIP meetings.

Have you seen this before?

A. I don't recall.

Q. I did not find any QSIP meeting minutes prior, dated prior to this one.

Were you aware of QSIP meetings prior to your employment at Actavis?

A. I don't recall.

Q. Was that something that you would want to review in your role as site quality head?

A. Possibly.

Q. Who would have called for these meetings?

A. The person running the QSIP program.

Q. Who ran the QSIP program in February of '07?

A. I'm not 100 percent sure.

Q. If you take a look at the attendees for subteam on labs, there is a list of names there.

Does reading those names help you recall

who was running QSIP at the time?

A. Are you referring to the time frame of February '07?

Q. Yes, I am.

A. Before I was employed at Actavis. Because the previous question you were asking, who ran QSIP before I came -- was employed at Actavis.

Q. Okay. I didn't catch myself on that.

All right. While you were employed at Actavis, beginning in January of '07, are you aware who was in charge of the QSIP plan?

A. I was.

Q. There you go.

Did you call these meetings?

A. Maybe not directly. I may have assigned someone to schedule the meetings.

Q. If we turn the page, to Page 2 of 6, did you run the meetings? Were you in charge?

A. I participated in the meetings.

Q. Was anyone in charge?

A. The agenda was what we were following.

Q. And who would conduct the communication in order to achieve the objective of the agenda?

A. We had a contractor at the time, Fernando.

Let's see if his name is on here.

If you see the third paragraph down, "Scott Talbot asked Fernando," Fernando was the one that was compiling all of the follow-up activities.

Q. Was Fernando with Quantic, if I'm saying that right?

A. I don't believe so.

Q. What was Quantic?

A. It was a consulting firm.

Q. Were they consulting regarding GMPs?

A. A portion of the GMPs.

Q. Were they on site at Actavis due to the observations of FDA inspections?

A. Yes.

Q. Would Quantic personnel sit in on the QSIP meetings?

A. No.

Q. Where it says, "Scott Talbot asked Fernando to research the following information" -- I'm sorry, who was Fernando again?

A. He was a contractor, so a consultant. I guess you would use that term.

Q. Do you recall what company he was with?

A. I don't recall.

Q. The second item under that says: "Existence of SOPs, DOIs, and definition of what to do if deviations are found."

Do you recall that to be with regard to the out-of-specification issues and SOPs that we discussed earlier?

A. I don't recall.

Q. What does "DOI" stand for?

A. Department Operating Instruction.

Q. What is the overall climate, if you will, of the quality department in February/March of 2007? And I guess specifically, is it business as usual or is there more emphasis on the heightened focus of GMPs, because of all of the regulatory issues?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Because of a new site head of quality, there were a lot of positive attitudes and there was a lot of changes being made.

BY MR. MILLER:

Q. And when you say "because of a new site head of quality," would you agree that that new site head of quality was instated due to regulatory

issues?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I don't recall.

BY MR. MILLER:

Q. Is there a sense that with regard to regulatory issues, if we don't do this right, the production line is going to be shut down?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: No.

BY MR. MILLER:

Q. So in light of multiple FDA inspections, 483 observations of which the company agreed, and a warning letter from the FDA, basically you felt it was business as usual?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: No.

BY MR. MILLER:

Q. No, you didn't feel like it was business as usual?

A. No.

Q. In your own words, how was it not business

as usual?

It's a tough one.

A. A lot of changes were being made to improve the process, to improve the systems.

Q. And that's based on regulatory compliance issues in the past?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: No.

BY MR. MILLER:

Q. Why were changes being made?

A. It's a continuous improvement process. Any time -- it's not specific to GMP issues, but any time you hire a new head of a department, that person is going to come in and make changes to that department for the better.

When I was hired as the site head of quality, and through my review and instructing people on reviewing items, when I felt improvements were needed to those documents or procedures I would instruct the folks how to do those improvements.

Q. Roughly 65 products were made at Actavis at Totowa?

A. I don't know how many products.

Q. Sixty-five, give or take 5?
A. I honestly don't know how many products we made.
Q. As a site quality head, it could have been 5, it could have been 100?
A. Well, it's not that broad of a range.
Q. You knew it was roughly 50, 70; is that fair?
A. You need to define the term "products."
Q. Pills in a bottle. You made pharmaceutical products; is that correct?
A. That's correct.
Q. I don't understand, define products.
A. Different strengths.
Q. If we're going to go to different strengths, you would agree it would be more like a hundred an -- gosh, I think I heard 110 or something.
A. And then differing package sizes.
Q. Then I want to define products. We will define products as a product, notwithstanding the different packages, different strengths. Digitek is one product.
How many products were made at Actavis

Totowa?

A. I don't know.

Q. Do you know that it is more than 200?

A. I don't know.

Q. All right. I will narrow it down in time. February of '07, you are the quality -- site head of quality.

A. Yes.

Q. I don't know why it's being so tough. At that time, did you have any idea how many products were being made?

A. Again, the term "products."

Q. I defined it.

A. Just to get clarity, it's active ingredients. You are referring to Digitek is a product made with Digoxin, which is an active ingredient.

Q. Yes.

A. So in the pharmaceutical world, compounds, if it is a specific compound. So we made Digitek in two different strengths.

Q. Yes.

A. And several different package sizes.

Q. Right.

A. But you're defining that as one product.
Q. I am.
A. So one compound.
Q. Yes.
A. It was more than five and less than 100.
Q. But you couldn't narrow it down any more than that?
A. No.
Q. So you wouldn't be surprised if it was six or you wouldn't be surprised if it was 99?
A. I would be surprised if it was six.
Q. Did you know there came a time that production of all products was ceased at Actavis?
A. Yes.
Q. Do you have an understanding of why that happened?
MR. ANDERTON: Objection. I instruct the witness to answer only with respect to Digitek.
THE WITNESS: Can you ask the question again?
BY MR. MILLER:
Q. Why was the production lines at Actavis shut down?
A. I don't know.

MR. ANDERTON: Again, I instruct the witness to restrict your answer to Digitek only, please.

THE WITNESS: I don't know.

BY MR. MILLER:

Q. Did you ever attempt to find out?

A. No. I did not work for Actavis Totowa at that time.

Q. At that time, you were a pharmaceutical manufacturing consultant?

A. No. I was working for Actavis South Atlantic.

Q. That's right.

Why did it come to be that in January of '08, you left Actavis Totowa and went to Actavis South Atlantic?

A. It was family reasons.

Q. And who filled your position at Actavis as site head of quality?

A. I don't believe anyone filled that position.

Q. Were you ever informed why the decision was made not to fill that position?

A. No.

BY MR. MILLER:

Q. Take a look at Observation 2.

Observation 2 is -- are you there?

A. Yes.

Q. "Laboratory records are deficient in that they do not include a complete record of all data obtained during testing."

Now, with that in mind, I want to read the paragraph regarding Ming Li back on Exhibit 155. And it states that Ming Li had indicated that he had received the new notebooks, that he was training on new documentation and data review procedures, and that he expects to finish the deliverable on improving the Little Falls data generation process on March 9th. He added that by March 5th, he expects to have trained all QC personnel on the new notebooks and on the new procedures.

My question is, were these new notebooks and procedures a response to the observations found by the FDA?

A. I don't know.

Q. Are you aware that there were lab notebook issues found during the FDA's inspections?

A. No.

Q. Take a look at Page 2 of 7 of Exhibit 155, at the bottom, where it starts out, "Scott Talbot." Let me know when you see that.

A. Yes.

Q. It reads, "Scott Talbot indicated that Quantic was finding cases where stability samples had not been tested within 30 days."

That Quantic, is that the consultant that we discussed earlier?

A. Yes.

Q. What is meant by -- or do you recall being told that there were cases where stability samples had not been tested within 30 days?

A. Yes.

Q. Is it a requirement that stability samples be tested within 30 days?

A. I don't know.

Q. Do you recall if it was an observation or finding from an FDA 483?

A. I don't know.

Q. Reflecting back on February of '07, after the FDA has been told that you're coming in to take over as site quality head, and you sent a letter to the FDA informing them that you're going to fill

that role, and a warning letter from the FDA in early February, what do you recall, as far as concerns or issues you wanted to tackle as the site head of quality?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I think it was just more communication and assuring people knew what their roles and responsibilities were.

BY MR. MILLER:

Q. Were you ever concerned that if you weren't successful in improving communication and identifying people's roles and responsibilities, that potentially all of the products at Actavis, production lines could be ceased?

A. No.

Q. No?

A. No.

Q. Were you ever -- did the concern ever -- strike that.

Did anything about your role, as site head of quality for Actavis in '07, lead you to believe that all production lines might be shut down at Actavis?

A. No.

Q. As you look back at it, I know you weren't there when the actual process shut down, was there anything or any incident or particular GMP violations that you thought, well, if this isn't put under control soon, that there might be the risk that all production might cease at Actavis?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: No.

BY MR. MILLER:

Q. Let's go to Page 5 of 7.

In this QSIP meeting minutes from February of '07, it starts out at the top of this page, "Scott Talbot."

Do you see the paragraph?

A. Yes.

Q. "Scott Talbot indicated that the Little Falls and Riverview validation master plans had been given to Alan Searles for revision, and that Alan will discuss those documents with other Actavis corporate individuals."

Did I read that correctly?

A. Yes.

Q. Do you remember Alan Searles?
A. Yes.
Q. What was this title?
A. I don't know.
Q. Am I correct in saying that the -- is this validation master plan, is it regarding the movement of the facilities from Little Falls to Riverview?
A. Partially.
Q. How so?
A. The validation master plan encompasses all sites, all three Actavis Totowa sites. Riverview was one portion of that master plan.
Q. Did it ever become an issue, as you recall, or if you recall, with the how the validation master plans were going to be transported, moved from the Little Falls facility to the Totowa facility?
A. You have to ask that question again.
Q. Certainly.
While you were the site head of quality for Actavis, was the company undergoing a move from Little Falls to Totowa?
A. Yes.
Q. And was part of the -- from a quality

perspective, transferring the validation master plan from one site to the other?

A. No.

Q. Then, doesn't the new site need to be validated?

A. Yes.

Q. Does that fall under the validation master plan?

A. Yes.

Q. It does.

Do you recall any issues from the FDA regarding how the validation on the new site was conducted?

A. No.

Q. I'm going to hand you what I'm going to mark as Exhibit 156.

(Thereupon, the referred-to document was marked by the court reporter for Identification as Deposition Exhibit 156.)

BY MR. MILLER:

Q. Am I correct in saying, sir, that this is also QSIP minutes but for meetings on March 5th, 6th, 7th and 8th of '07?

A. It appears, yes.

A. Yes.
Q. And were you present during that inspection?
A. Yes.
Q. And let's see, the inspector's name is difficult to read, but the signature at the bottom looks like Kristy.
Do you recall her?
A. Yes.
Q. Do you recall other inspectors being there as well or just her?
A. No other inspectors.
Q. Observation 1 discusses an FDA -- or a field alert report. Is that something that falls under your title as site head of quality?
A. Yes.
Q. What is an NDA field alert?
A. It's a form that's completed to notify the FDA of products in the market that may have -- be impacted with compliance issues.
Q. So it's part of your job title and responsibility to keep the FDA informed if there are issues with the product?
A. Product in the market.

very difficult to meet. But five days is a pretty reasonable time frame to notify the FDA, to allow us to do our full investigation, to determine that there are specific lots in the market that may be impacted.

Q. So if I could kind of put it in different words, you agree with the importance of timely notification, the requirements of three days were difficult to meet, you responded within five days and felt that was appropriate?

A. Yes.

Q. But you are not taking anything away from the significance of getting the report out there?

A. The timeliness of the report, yes.

Q. Let's take a look at Observation 3. It says: "Written production and process control procedures are not followed in the execution of production and process control functions.

"Specifically, the Standard Operating Procedures, 'Investigation of Deviations,' SOP No. 33, and 'Investigation of Out-of-Specification Results,' DOI No. QC 59, are not followed in that investigations are not initiated when a deviation or out-of-specification result is detected and are not

closed within 30 days.

"In addition, interim reports are not always written to document justification for investigations to remain open after each 30-day interval."

Were you present with the investigator when it was discovered that this information came to the surface?

A. Yes.

Q. And did you agree with these findings?

A. Yes.

Q. And as the site head of quality, how did you handle the fact that SOP No. 33, investigations into deviations, were not followed?

A. We enforced the fact that an interim report needs to be written for investigations that extend beyond 30 days.

Q. Did this bring a heightened focus of awareness of following SOPs, specifically the investigation of deviations?

A. No.

Q. When we talked about the SOP that was on file regarding out-of-specification results, would that be the particular SOP?

A. Yes.

Q. And so there is an SOP regarding out-of-specification results, and there's also a department instruction on out-of-specification results?

A. No.

Q. Then what is the purpose and intent of what they address here as the parenthetical, investigation of out-of-specification results, end of parenthetical, department of --

A. Operating.

Q. Thank you. Department operating instruction No. QC 59?

A. The FDA was using SOP for both those documents. Their terminology, SOP, fits both SOP and DOI in the Actavis system.

Q. Is there in fact a department operating instruction QC 59 for the investigation of out-of-specification results?

A. Yes.

Q. And is there an SOP No. 33 for investigation of deviations?

A. Yes.

Q. And you agree that neither one of those

were followed?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Specific to not closing investigations within 30 days. Or writing interim reports if they extended beyond 30 days.

BY MR. MILLER

Q. You recall out-of-specification issues being at the forefront of the letter to the FDA from Divya Patel, the attachment of out-of-specification results?

You can take a look at that. It would be one of the earlier exhibits. There was an attachment that listed all out-of-specification tablets.

That's Exhibit 149.

A. Ask the question again, I'm sorry.

Q. Certainly.

Out-of-specification was one of the primary concerns of the letter from the president of Actavis Totowa to the FDA when you began your work as the site head for quality, correct?

MR. ANDERTON: Objection, mischaracterizes

the document.

You may answer.

THE WITNESS: I want to say that the FDA requested that we send them a list, and I don't think that this was stating a concern with OOSs. It was providing a list as requested by the FDA.

BY MR. MILLER:

Q. And you don't think that request had anything to do with the 483 observations?

A. I don't know.

Q. Was Actavis Totowa found to be in violation of a GMP regarding out-of-specification results during this inspection, September of '07?

A. No.

Q. So, okay. Is it your testimony that written production and process control procedures not being followed in the execution of production and process control functions, as written, is not a violation of GMP?

A. Can you repeat the question?

Q. Certainly. Is the Observation 3, as written, a violation of GMP?

A. Yes.

Q. And you disagree with the observation?
A. Yes.
Q. Did you agree with any of the findings of the FDA in this inspection?
A. I don't recall.
Q. Well, let's take a look at them. We talked about the first one. We covered Observation 1.

Observation 2, the written stability testing program is not followed.

Do you recall being with the inspector when that issue arised during the inspection?

A. I don't recall.
Q. Do you, as you sit here today, recall agreeing or not agreeing with that finding?
A. I don't recall.
Q. Those are the only three observations of this FDA inspection.

Do you have a sense whether you passed or failed this inspection?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I don't know either way.

pre-written statement about that observation?
A. Yes.
Q. And would you agree that those pre-written statements define a violation of a GMP?
A. Yes.
Q. And would you agree that it would take an observation of a violation in order to trigger the inspector selecting an entry from the Turbo 483?
A. Yes.
Q. Would you agree that Observation 3 as written and observations in general relate to the violation of the GMP and aren't specific to any particular product?
A. No.
Q. Was Digitek a product that Actavis was manufacturing in September of 2007?
A. Yes.
Q. The GMP, the standard that is addressed in this observation, written production and process control procedures are not followed in the execution of production and process control functions, would you agree that that pertains to the Digitek product as well?
MR. ANDERTON: Objection.

Q. The Quality, Production Laboratory Control, Materials and Facilities and Equipment Systems were covered during the current inspection and corrections made since the previous inspections were verified.

An FDA 483 inspectional observation was issued at the closeout meeting regarding deficiencies in the areas of field alerts, the stability testing program and investigations.

Did I read that correctly?

A. Yes.

Q. Then it goes on to say in addition a discussion was held with management regarding additional items not listed on the FDA 483.

Do you recall, or were you part of the conversations with management as a result of this inspection?

A. Yes.

Q. Do you recall additional items that were addressed as a result of this inspection that were not listed on the FDA 483?

A. Yes.

Q. And what were some of those additional items?

A. I don't recall.
Q. You recall the fact that there were additional items?
A. Yes.
Q. You don't recall what they were specifically?
A. Yes.
Q. Corrections were promised for all observations and discussion items.
Were you involved in discussing what the correct -- what corrections were promised?
A. Yes.
Q. Who else would have been -- how did that take place, would it be you sitting down at a meeting with the inspector?
A. Yes.
Q. Who else would be present?
A. It would be a variety of people. I'm not specific who was there, but it is representatives from the company.
Q. When it came to the issue of investigations, do you recall who would have been present for the meeting discussing the corrections for the issues with investigations?

MR. ANDERTON: Pete, I want to, so we all know where we are. You say Observation 1. What document? What --

MR. MILLER: I was in the middle of doing that. I guess I should have done that first.

MR. ANDERTON: Just so that, as we all sit here and as somebody else listens or reads it later, we know exactly what we are talking about.

MR. MILLER: I'm with you.

All right. Then help me out. What is the exhibit number that I just marked.

MR. ANDERTON: 158.

BY MR. MILLER:

Q. Looking at Exhibit 158, the Establishment Inspection Report from September of 2007, Page 25 of 40, the voluntary corrections outlined in Observation 1, you would agree, are Observation 1 from the 2006 FDA 483?

A. From the inspection that occurred in July and August of 2006.

Q. Okay. So if I read Observation 1 on Exhibit 68, the August '06 report, and then I look at the Page 25, '07 from the Establishment

Inspection Report from September of '07, both observations read the same, you agree, quality control unit lacks authority to fully investigate errors that have occurred?

A. Yes, that sentence reads identical.

Q. Do you agree that that, as written, is a violation of cGMP?

MR. ANDERTON: That is what as written?

MR. MILLER: What I just read?

Observation 1.

THE WITNESS: Yes.

BY MR. MILLER:

Q. Do you agree that it applies to all products?

A. It --

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: It may apply to all products.

BY MR. MILLER:

Q. What information would you need for you to believe that it didn't apply to all products?

A. I would need to look at what documents the FDA reviewed during this inspection. And determine

(Thereupon, the referred-to document was marked by the court reporter for Identification as Deposition Exhibit 159.)

MR. ANDERTON: 159?

MR. MILLER: 159.

BY MR. MILLER:

Q. It is a few pages there. Take a look at it and when you are ready, I will ask you questions.

A. Okay.

Q. The document is titled, "Blend Failure Investigation."

Now, have you seen this document before?

A. I don't recall.

Q. Do you recall investigations into blend failures?

A. Yes.

Q. Okay. And those investigations into blend failures were not, do you agree with me, not product specific?

A. I think this is -- okay. Blend OOSs, I think we need to kind of distinguish between failures and OOSs.

Q. Certainly.

A. You can have an OOS in the laboratory, and

through additional testing find that the blend did not fail. That the OOS was caused due to analytical or sampling error.

So when -- I would like to just assure we are clear on what a blend failure is versus a blend OOS.

Q. Okay. So it is your testimony that this concerns blend failures and not OOSs?

A. I'm thinking -- I need to read a little further, but it appears it is covering both OOSs and blend failures, so it is a combination of two.

Q. It was a combination of the two, was it something that was usually addressed at the same time?

A. Yes, an OOS may result in a blend failure. But an OOS may also not result in a blend failure.

Q. Do you have an understanding or memory as to why blend failure would be a specific investigation separate and apart from an out of specification investigation?

A. When we have multiple out of specifications that have a similar theme to them, you would then investigate it as an encompassing one investigation.

if a deviation is necessary.

"Also the draft protocols need to be modified to reduce the number of samples. We do not need nearly 200 samples to show the process results in a uniform product."

Did I read that correctly?

A. Yes.

Q. And you were addressing, am I accurate in saying, the validation process of the move?

A. The transfer confirmation of lots.

Q. Is the transfer confirmation associated with the validation?

A. I don't believe so.

Q. If I were to go to Exhibit 26, which I just handed to you, and went to observation, I believe it is 5.

Observation 5, the first portion of it, laboratory controls do not include the establishment of scientifically sound and appropriate specifi-cations and test procedures designed to assure that components, in process materials and drug products conform to appropriate standards of identity, strength quality and purity."

Did I read that correct?

A. Yes.
Q. And it goes on to say, Specifically, analytical method transfers for each method line from the Little Falls, New Jersey quality control laboratory to the new Totowa, New Jersey quality control laboratory were not conducted. Only two types of analytical methods, HPLC and GC, were used to support the analytical transfer of approximately, redacted, in process, finished product and stability methods. There were no analytical method transfers for such techniques as dissolution, atomic absorption, loss on drying and blend testing.
Did I read that correctly?
A. Yes.
MR. ANDERTON: Objection.
You may answer.
BY MR. MILLER:
Q. Is there a correlation between this finding and the subject of this e-mail chain that we have discussed as Exhibit 160?
A. No.
Q. Then if you would explain to me what is the difference between -- I'm sorry. What is the term you use for the topic at issue here, Exhibit

160?

A. This is talking specifically on the number of samples to be pulled for testing.

Q. Is that related to the move? Is it something that has to be done above and beyond what is typically done in the ordinary course of business because of the move?

A. Yes.

Q. And how does the task of this described in Exhibit 160 differ from analytical method transfers?

A. This is a laboratory test method. So this is the testing of the product in the laboratory. This is sampling of the process in manufacturing.

Q. Going back to Exhibit 26, Observation 5, were you ever aware of the fact, as it is outlined here, regarding analytical method transfer?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Yes, we had a transfer protocol that we used.

BY MR. MILLER:

Q. Did you ever subsequently learn that the FDA had written up an observation regarding that analytical --

A. No.
Q. -- transfer?
Do you agree or disagree with the findings I just read for Observation 5?
MR. ANDERTON: Objection.
You may answer.
THE WITNESS: I don't know.
BY MR. MILLER:
Q. If you would take a look again at Exhibit 159 and I want to go to and have it handy, going back to Exhibit 26, the inspection report from May of '08. Specifically I would like to look at Observation 4, which is Page 6 of 16.
Do you see Observation 4?
A. Yes.
Q. It says, "On determinations of conformance to appropriate written specifications for acceptance are deficient for in process materials."
Do you see that?
A. Yes.
Q. And it goes on to say specifically, "Although three out-of-specification results were obtained for blend uniformity at the right top sample location for Digoxin tablets, .125 milli-

As you sit here, were you aware that lot 70148 was not released?

A. I don't know.

Q. Would you be involved, as a site head of quality for Actavis, in the decision to not release a lot?

A. Yes.

Q. How does it typically happen that you are involved in a lot not being released?

A. The investigations that are conducted, all analytical results that are reported come through the site head of quality to be signed off.

Q. Do you recall how often it would come to be in your position that a lot for any product would not be released? Is this something that would happen daily or weekly?

A. Very infrequent.

Q. Okay. But this particular one you don't recall?

A. No.

Q. As we sit here today, do you agree or disagree that no manufacturing investigations were conducted regarding these out of specification findings?

A. I don't recall.
Q. Were there any changes to that document as far as you know from the time you started and first generated the document until the time you left in January of 2008?
A. I don't know.
Q. And the responsibilities of quality unit, did you say that is an SOP or DOI?
A. I'm not sure. But it is SOP or DOI.
Q. Does Dan Bitler have the authority to not release a batch or lot?
A. Yes.
Q. And if Dan Bitler elected to not release a batch or lot, is he required to report that to you?
A. I don't know if he's required, so no.
Q. So he could stop the release of a lot or batch and there is no requirement that he informed you?
A. Not that I'm aware of.
Q. Are you aware if that ever happened while you were acting as site head of quality?
A. No.
Q. The Page 3 of 67, Actavis 003319, it is a description of the, I will call it the incident, if

Q. Were you aware that double thick tablets were found out in the field?
A. No.
MR. ANDERTON: Objection.
You may answer.
THE WITNESS: No.
BY MR. MILLER:
Q. Quality is design -- or quality of a tablet -- do you agree or disagree with this statement, the quality of a tablet is that it has the purported identity, strength, quality that it is supposed to have, correct?
A. Yes.
Q. And that is for other reasons, but for safety?
A. Yes.
Q. And as the site head for quality, one of your job descriptions or duties is to make sure that a tablet that gets out to the consumer is safe?
MR. ANDERTON: Objection.
You may answer.
BY MR. MILLER:
Q. Do you agree?
A. Yes.

Q. If double thick tablets are found in a lot, is there the potential that double thick tablets are going to make it out to consumers?

A. There is always a potential.

Q. Is it important to know, through testing, what that double thick tablet contains?

A. No.

Q. And this page we are looking at talks about the test being a description test, identification A test, identification B test.

Am I reading that correct?

A. Yes.

Q. And we turn the page, we tested for friability, assay by HPLC, uniformity of dosage.

These are all the standard tests that are conducted of a typical lot and batch?

A. Yes.

Q. And these are tests that could have been done on a double thick tablet, is that correct?

MR. ANDERTON: Object to the hypothetical.

You may answer.

THE WITNESS: Could have been, yes.

that correct?

A. Not at 1/25/08, no.

Q. 1/25/08 is the date the investigation was signed, is that correct?

A. I don't know.

Q. Do you agree with the findings of this observation?

A. I can't answer. Because I don't know what this is all referring to. The investigation may have looked at all of the lots on the market, the 89 of the .125 and the 78 of the .25, but not to the satisfaction of the investigator.

So I don't know. I can't answer that question.

Q. So, as you sit here, you are saying possibly it was looked into, all of the other lots?

A. Yes. Yes.

Q. Let's go to Observation 11, Page 14 of 16.

Observation 11, are you there?

A. Yes.

Q. Drug product production and control records are not reviewed and approved by the quality control unit to determine compliance with all established approved written procedures before a

batch is released or distributed.

Did I read that correctly?

A. Yes.

Q. As written, is that a violation of GMP?

A. Yes.

Q. Okay. It goes on to say, well, it is, as the site head for quality, are you the one who would sign approving as the quality control unit?

A. No.

Q. Who would?

A. Dan Bitler.

Q. Well, let's read on. Specifically, investigations of deviation reports require a review of quality assurance and approval by regulatory affairs, quality compliance and an approval of product disposition by the head of quality assurance. On multiple occasions, these three signatories were completed by the same individual.

For example, redacted, regarding double thick, redacted, was signed by the director of quality assurance under the sections designated for quality assurance, regulatory affairs, quality compliance and the head of quality assurance.

Were you a part of the discussions when

Did I read that correctly?

A. Yes.

Q. Do you agree that while you were site head of quality that no products were being made by Actavis that had Narrow Therapeutic Index?

A. I don't know.

Q. Were any products being made in Actavis as you were site head of quality with the specification 95 to 105 percent as you address here at the bottom of the e-mail?

A. I don't know.

MR. MILLER: I'm going to hand you what I will mark as Exhibit 165.

(Thereupon, the referred-to document was marked by the court reporter for Identification as Deposition Exhibit 165.)

MR. ANDERTON: Thank you.

165.

MR. MILLER: Yes.

MR. ANDERTON: Thank you.

BY MR. MILLER:

Q. Do you recall seeing this e-mail in the past?

A. No.

moment. Please talk with the QC Lab."

You don't recall the president of Actavis passing that information on to you?

MR. ANDERTON: Objection.

Are you talking about Dan Bitler?

MR. MILLER: Oh, I'm sorry. I stand corrected.

BY MR. MILLER:

Q. Dan Bitler, the director, I believe you said, of quality assurance.

A. Yes. This is from Dan Bitler.

Q. So do you recall the director of quality assurance informing you the information about the assay ranges?

A. No.

Q. Do you know what he means by "assay range"?

A. Yes. This is the content of drug, the active ingredient in the tablets.

Q. And you agree that these drugs have a tighter range for assay?

A. Define "tighter."

Q. Certainly.

Other products have a wider range of

assay?

MR. ANDERTON: Objection.

BY MR. MILLER:

Q. Do you understand what I mean by "wider"?

A. These -- these specifications are reviewed and approved by the FDA, so if they want the range to be 95 to 105, we will move that range to be more limited.

These aren't -- I mean, you say there are some that we are allowed 90 to 110, so, yes, in some cases, these specifications are more narrow than others.

Q. Narrow.

So you agree that Digoxin has a more narrow range for assay?

A. More narrow compared to?

Q. Other products.

A. Well --

MR. ANDERTON: Objection.

You may answer, if you understand it.

THE WITNESS: No, because there -- like Quinaretic has 95 to 105. So Digoxin is not more narrow than other products.

(Thereupon, a discussion was held off the record, after which the following proceedings were held:)

THE VIDEOGRAPHER: We are back on video record.

MR. ANDERTON: I have no further questions of this witness.

MR. MILLER: Sir, just a couple of follow-ups and we will be done.

F U R T H E R E X A M I N A T I O N

BY MR. MILLER:

Q. In reference to the many questions about the corrections that were identified in the establishment investigation report and your testimony that that closes out the observation, you will agree with me that certainly when the FDA comes back to investigate again there is always that risk that they will find similar observations?

A. Yes.

Q. And, in fact, they did come back and investigate in '08 in which you were there to assist the investigators?

A. Yes.

Q. And you would agree that that

investigation resulted in having the entire production line at Actavis shut down?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: As a result of the inspection, it was a decision by management to shut down production, yes.

BY MR. MILLER:

Q. Would you agree that is the most serious finding or action that can come out of an FDA inspection?

A. No.

Q. What is more serious?

A. The injunction.

Q. An injunction. Which is the FDA instructing that you shut down?

A. Yes.

Q. When you were asked about launching new products, given that all products, production line for all products was shut down, you would agree that whatever products were launched prior to April of '08, those products had to be shut down as well?

A. Yes.

MR. MILLER: I have no further questions.

AFFIDAVIT

STATE OF FLORIDA)
COUNTY OF)

I, , being first duly sworn, do hereby acknowledge that I did read a true and certified copy of my deposition which was taken in the case of IN RE: DIGITEK PRODUCTS LIABILITY LITIGATION, taken on the 25th day of January, 2010, and the corrections I desire to make are as indicated on the attached Errata Sheet.

CERTIFICATE

STATE OF FLORIDA)
COUNTY OF)

Before me personally appeared _____, to me well known / known to me to be the person described in and who executed the foregoing instrument and acknowledged to and before me that he executed the said instrument in the capacity and for the purpose therein expressed.

Witness my hand and official seal, this _____ day of _____, _____.

_____
(Notary Public)

MY Commission Expires:

CERTIFICATE OF OATH

STATE OF FLORIDA)

COUNTY OF MIAMI-DADE)

I, the undersigned authority, certify that SCOTT TALBOT personally appeared before me and was duly sworn.

WITNESS my hand and official seal this 2nd day of February, 2010.

KELLI ANN WILLIS, RPR, CRR
Notary Public, State of Florida
My Commission No. DD911443
Expires: 2/16/12

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CERTIFICATE

STATE OF FLORIDA)

COUNTY OF MIAMI-DADE)

I, KELLI ANN WILLIS, Registered Professional Reporter and Certified Realtime Reporter do hereby certify that I was authorized to and did stenographically report the foregoing deposition of SCOTT TALBOT; That a review of the transcript was requested; and that the transcript is a true record of my stenographic notes.

I FURTHER CERTIFY that I am not a relative, employee, attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

Dated this 2nd day of February, 2010.